type double patenting. Applicants have amended claims 1, 19, and 20 to include the recitation "wherein the cross-linking agent is an aldehyde," which recitation is found in original claim 12. Claim 12 was determined to be non-coextensive and patentably distinct compared to claims in copending application Serial No. 09/598,571. Applicants assert that the claims as amended are improperly rejected for double patenting and request reconsideration and withdrawal of this ground of rejection.

Response to Section 102 Rejection

Claims 1-12, 15-18 and 20 were rejected under 35 U.S.C. § 102(e) for being anticipated by Dunphy U.S. Patent No. 5,679,333. The Examiner contends that the "solution as disclosed by Dunphy [citing to column 3, lines 55-67; column 4, lines 16-18; and Example 2] contains the same ingredients as the solution recited in the claims of the instant invention and thus possesses the inherent properties of being capable of storing cells to be analyzed directly by both cytological and molecular methods." In light of the amendment to the claims, applicants respectfully disagree with this ground of rejection. The present claims describe a cross-linking agent that is an aldehyde comprising about 1% to about 15% of the medium. Nowhere does Dunphy teach a medium comprising a preservative, an anti-degradation agent and an aldehyde cross-linking agent comprising about 1% to about 15% of the medium. Therefore, applicants respectfully request reconsideration and withdrawal of this ground of rejection.

Response to Section 103 Rejection

Claims 21-23 were rejected under 35 U.S.C. § 103(a) for being unpatentable over Wainwright U.S. Patent No. 5,370,128 in view of Dunphy U.S. Patent No. 5,679,333. The Examiner contends that Wainwright teaches an article of manufacture and that Dunphy teaches a preservation fluid. In light of the amendment to the claims, Applicants respectfully disagree with

this ground of rejection.

To establish a *prima facie* case of obviousness, the combination of references must teach or suggest all the claim limitations. However, the combination of Wainwright and Dunphy does not teach or suggest a medium comprising a cross-linking agent that is an aldehyde comprising about 1% to about 15% of the medium. Therefore, in light of the amendment to the claims and the arguments presented above, applicants respectfully request reconsideration and withdrawal of this ground of rejection.

AUTHORIZATION

No additional fee is believed to be necessary. The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2629-4005US1.

Respectfully submitted,

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Dated: March 20, 2001

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APPENDIX

1. (twice amended) A cell or tissue collection medium [referred to as a universal collection medium], wherein the cells or tissue contained in the medium can be analyzed directly by both cytological and molecular methods, wherein the molecular method of analysis comprises either RNA or DNA or protein analysis or the analysis of both RNA and DNA, and wherein the medium is water based and comprises a preservative, a cross-linking agent and an anti-degradation agent, and wherein the cross-linking agent is an aldehyde comprising about 1% to about 15% of the medium.

2. (amended) The [universal collection] medium of claim 1, wherein the medium consists of a volume of less than 10 ml.

3. (amended) The [universal collection] medium of claim 1, wherein the medium consists of a volume of less than about 5 ml.

4. (amended) The [universal collection] medium of claim 1, where in the medium consists of a volume of less than about 2 ml.

5. (twice amended) The [universal collection] medium of claim 1 wherein the [universal collection] medium comprises a buffer component, at least one alcohol component, a cross-linking agent and an agent to inhibit degradation of at least one of the group consisting of RNA, DNA, and protein.

6. (amended) The [universal collection] medium of claim 5, wherein the buffer component has a buffering capacity within a pH range of about 2.5 to about 6.

7. (amended) The [universal collection] medium of claim 6, wherein the buffer component has a buffering capacity within a pH range of about 3 to about 5.

8. (amended) The [universal collection] medium of claim 7, wherein the buffer component has a buffering capacity within a pH range of about 3.5 to about 4.5.

9. (amended) The [universal collection] medium of claim 5, wherein the alcohol component comprises a C1 to C10 alcohol.

10. (amended) The [universal collection] medium of claim 9, wherein the alcohol component is selected from the group consisting of methanol, ethanol, propanols, butanols, and pentanols.

11. (amended) The [universal collection] medium of claim 10, wherein the alcohol component comprises ethanol or n-butanol.

13. (amended) The [universal collection] medium of claim 12, wherein the cross-linking agent is selected from the group consisting of formaldehyde and glutaraldehyde.

14. (amended) The [universal collection] medium of claim 13 [12], wherein the cross-linking agent comprises glutaraldehyde-bisulfite.

15. (twice amended) The [universal collection] medium of claim 5, wherein the agent to inhibit degradation of at least one of the group consisting of RNA, DNA, and protein comprises at least one agent selected from the group consisting of a nuclease inhibitor, a protease inhibitor and a chelating agent.

16. (twice amended) The [universal collection] medium of claim 15, wherein the agent to inhibit degradation of at least one of the group consisting of RNA, DNA, and protein comprises a chelating agent.

17. (twice amended) The [universal collection] medium of claim 15, wherein the chelating agent is selected from the group consisting of murexide, chromotropic

acid, 1-(1-hydroxy-2-napththylazo-2-hydroxy-5-nitronaphthalene-4-sulphonic acid, EDTA (ethylenediaminetetraacetic acid), *o*-phenanthroline, and thiourea.

18. (amended) The [universal collection] medium of claim 15, wherein the chelating agent comprises EDTA (ethylenediaminetetraacetic acid).

19. (amended) A method of performing morphological and biochemical analysis on a cell or tissue, wherein the method comprises:

obtaining cells or tissues from a patient;

preserving the cells or tissue in a water-based medium comprising a preservative, a cross-linking agent and an anti-degradation agent, and wherein the cross-linking agent is an aldehyde comprising about 1% to about 15% of the medium;

directly analyzing the morphology of the cells or tissue preserved in the medium; and

directly analyzing either RNA or DNA or protein contained in the cells or tissue preserved in the medium.

20. (twice amended) A [universal] collection medium comprising water, a preserving agent, a buffer, a cross-linking agent and an agent capable of inhibiting the degradation of at least one of the group consisting of RNA, DNA, and protein, wherein the cross-linking agent is an aldehyde comprising about 1% to about 15% of the medium.

26. (amended) The method of claim 24, [wherein the method of claim 24,] wherein the cells are stored in a sample of less than about 5 ml.

29. (new) The method of claim 19, wherein the cross-linking agent is selected from the group consisting of formaldehyde and glutaraldehyde.

30. (new) The medium of claim 20, wherein the cross-linking agent is selected from the group consisting of formaldehyde and glutaraldehyde.

31. (new) The article of claim 21, wherein the cross-linking agent is selected from the group consisting of formaldehyde and glutaraldehyde.

32. (new) The method of claim 24, wherein the cross-linking agent is selected from the group consisting of formaldehyde and glutaraldehyde.

33. (new) The medium of claim 1, wherein the cross-linking agent comprises about 1% to about 5% of the medium.

34. (new) The method of claim 19, wherein the cross-linking agent comprises about 1% to about 5% of the medium.

35. (new) The medium of claim 20, wherein the cross-linking agent comprises about 1% to about 5% of the medium.